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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,305	09/28/2001	Jennifer Richardson	07334-312001 / MPI2000-31	5199
26161	7590	08/30/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 08/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/967,305	Applicant(s) RICHARDSON ET AL.	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 06 July 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 33-34, for reasons already of record, because the amendment is not and will not be entered.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment is not and will not be entered because the amendment raises new issues:

1) New Claims 59-79 require new 112, first paragraph, written description and scope rejection, due to the language a nucleic acid probe "comprising" at least 15, 20, 25, 30, 40, 50, 75, 260, 300, 400, 500, 800, 900 consecutive nucleotides, and the "complement" of SEQ ID NO:3.

2) New Claims 71-72 require new objection, because they are duplicate.

The following are answers to Applicant's arguments.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Rejection under 35 USC 112, second paragraph of claim 34 pertaining to being indefinite, remains for reasons already of record in paper of 01/02/04.

Applicant asserts that claim 34 has been amended to recite specific stringent hybridization and wash conditions.

Applicant's arguments set forth in paper of 06/04/04 have been considered but are not deemed to be persuasive for the following reasons:

Applicant's arguments are moot in view that the amendment is not and will not be entered.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH

1. Rejection under 35 USC 112, first paragraph of claims 33-34, pertaining to lack of enablement for a method for identifying candidate therapeutic agents for the treatment of cancer remains for reasons already of record in paper of 01/02/04.

Applicant argues that inhibition of racemase mRNA reduces the proliferation of prostate cancer cells. Applicant submits a new reference by Zha et al, which teach that proliferation of a prostate cancer cell line is impaired by small interference RNA which reduces the expression of the racemase enzyme.

Applicant's arguments set forth in paper of 06/04/04 have been considered but are not deemed to be persuasive for the following reasons:

Applicant's arguments are moot in view that the amendment is not and will not be entered, and the reference by Zha et al is not considered.

Applicant asserts that a) racemase mRNA and protein is expressed at a higher level in actual clinical prostate tumor sample and prostate metastasis as compared to normal prostate tissue, as taught by Beach et al, Kuefer et al, Luo et al, Rubin et al, and Jiang et al, b) expression of racemase may play a role in the development and or progression of prostate cancer, as taught by Luo et al, c) variants of racemase are associated with cancer risk, as taught by Zheng et al. Applicant argues that the claims are enabled irrespective of the unpredictability of gene therapy or antisense therapy.

Applicant argues that the Examiner concerns are misplaced and undue. Applicant asserts that there remain many, many compounds, e.g. small molecules, that can be screened and may prove to be useful therapeutic agent.

Rejection remains because there is no correlation between reduction of the racemase expression and treatment of prostate cancer. It is unpredictable that any of the screened compounds would have therapeutic effect for the treatment of prostate cancer, in view of the teaching in the art that anticancer drug discovery for cancer therapy treatment is unpredictable as taught by Gura et al, , 1997, Jain et al, Curti et al and Hartwell et al, all of record, and further in view that gene therapy and in vivo therapy using antisense is unpredictable, as taught by Gura, 1995, Wang et al, Doenarain et al, Miller et al, Verma et al, Crystal et al, all of record.

Further, contrary to Applicant arguments, the Examiner's recitation that gene therapy and antisense therapy are unpredictable is not misplaced and undue, because it is in view of this unpredictability, that one cannot predict that the compounds screened by the claimed method would be useful for treating for treating prostate cancer.

Thus, the scope of the claims encompasses identifying compounds that not only inhibit the expression of SEQ ID NO:3, but also could be used for treating prostate cancer, a process which is beyond the enablement of the instant application.

2. Rejection under 35 USC 112, first paragraph of claim 34, pertaining to lack of enablement for a method for identifying candidate therapeutic agents for the treatment of cancer, using as probe a nucleic acid molecule which hybridizes to the alpha-methyl-CoA racemase mRNA under the hybridization conditions recited in claim 34 remains for reasons already of record in paper of 01/02/04.

Applicant asserts that claim 34 has been amended to delete "selectively" hybridizes and recite specific stringent hybridization and wash conditions. Applicant

argues that nucleic acid molecule that hybridizes to racemase mRNA under stringent hybridization conditions is a probe that is sufficiently specific for racemase mRNA to identify racemase mRNA. Applicant argues that those skilled in the art routinely use probes that hybridizes under stringent hybridization and washing conditions to a particular nucleic acid molecule to identify and quantify the particular nucleic acid molecule. Applicant asserts that thus, the hybridizing nucleic acid molecule in claim 34 is defined in a manner that allows one of ordinary skill in the art to use the claimed method.

It is noted that the amendment is not and will not be entered.

Applicant's arguments set forth in paper of 06/04/04 have been considered but are not deemed to be persuasive for the following reasons:

Contrary to Applicant arguments, the hybridizing nucleic acid molecule for use in the claimed method is not defined. The claimed nucleic acid molecule encompasses any sequence of any structure, which are attached to a fragment of SEQ ID NO:3, via which the claimed nucleic acid molecule hybridizes to the racemase of SEQ ID NO:3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

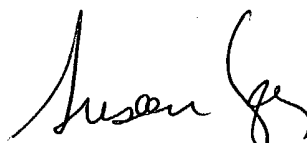
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

August 25, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish at the end.